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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 03/20/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/359,426

Applicant(s)

Cripps et al.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 13, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 7-9, 18-22, and 24-27 ~~is/are~~ pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 7-9, 18-22, and 24-27 ~~is/are~~ rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 01/13/03 (paper no. 20) in response to the non-final Office Action mailed 07/12/02 (paper no. 18). With this, Applicants have amended the specification.

Status of Claims

- 2) Claims 2, 3, 5, 6, 10-17, 23 and 28-35 have been canceled via the amendment filed 01/13/03. Claims 1, 4, 7-9, 18-22 and 24-27 have been amended via the amendment filed 01/13/03. Claims 1, 4, 7-9, 18-22 and 24-27 are under examination.

Specification

- 3) The amendment introduced to pages 2 and 7 of the specification via the amendment filed 01/13/03 does not identify the amino acid sequences longer than four amino acids with SEQ ID NO. as required under 37 C.F.R. 1.821 through 1.825. Any sequences recited in the instant specification which are encompassed by the definitions for nucleotide and/or amino acid sequences as set forth in 37 C.F.R. 1.821(a)(1) and (a)(2) must comply with the requirements of 37 C.F.R. 1.821 through 1.825. Note that branched sequences are specifically excluded from this definition.

APPLICANT MUST COMPLY WITH THE SEQUENCE RULES WITHIN THE SAME TIME PERIOD AS IS GIVEN FOR RESPONSE TO THIS ACTION, 37 C.F.R. 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. 1.821(g).

Objection(s) Moot

- 4) The objection to claim 3 made in paragraph 21(a) of the Office Action mailed 07/12/02 (paper no. 18) is moot in light of Applicants' cancellation of the claim.

Objection(s) Withdrawn

- 5) The objection to the specification made in paragraph 8(i) of the Office Action mailed 07/12/02 (paper no. 18) is withdrawn in light of Applicants' amendments to the specification.
- 6) The objection to the specification made in paragraph 8(ii) of the Office Action mailed 07/12/02 (paper no. 18) is withdrawn in light of Applicants' amendment to the specification.
- 7) The objection to the specification made in paragraph 8(iii) of the Office Action mailed

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07/12/02 (paper no. 18) is withdrawn in light of Applicants' amendment to the specification.

8) The objection to the specification made in paragraph 8(iv) of the Office Action mailed 07/12/02 (paper no. 18) is withdrawn in light of Applicants' amendment to the specification.

9) The objection to claims 1, 18 and 19 made in paragraph 21 of the Office Action mailed 07/12/02 (paper no. 18) is withdrawn in light of Applicants' amendment to the claims.

Rejection(s) Moot

10) The rejection of claims 2, 3, 5 and 6 made in paragraph 9 of the Office Action mailed 07/12/02 (paper no. 18) under 35 U.S.C. § 101, as being directed to a non-statutory subject matter, is moot in light of Applicants' cancellation of the claims.

11) The rejection of claims 2, 3, 5, 6, and 23 made in paragraph 10 of the Office Action mailed 07/12/02 (paper no. 18) under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable, is moot in light of Applicants' cancellation of the claims.

12) The rejection of claims 2, 3, 5, 6 and 23 made in paragraph 11 of the Office Action mailed 07/12/02 (paper no. 18) under 35 U.S.C § 112, first paragraph, as being non-enabled, is moot in light of Applicants' cancellation of the claims.

13) The rejection of claim 6 made in paragraph 13(a) of the Office Action mailed 07/12/02 (paper no. 18) under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

14) The rejection of claims 2 and 6 made in paragraph 13(b) of the Office Action mailed 07/12/02 (paper no. 18) under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

15) The rejection of claims 5 and 23 made in paragraph 13(c) of the Office Action mailed 07/12/02 (paper no. 18) under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

Rejection(s) Withdrawn

16) The rejection of claims 1, 4 and 7-9 made in paragraph 9 of the Office Action mailed 07/12/02 (paper no. 18) under 35 U.S.C. § 101, as being directed to a non-statutory subject matter, is withdrawn in light of Applicants' amendment to the claims and/or the base claim.

- 17) The rejection of claims 8, 18, 22, 25 and 26 made in paragraph 10 of the Office Action mailed 07/12/02 (paper no. 18) under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable, is withdrawn in light of Applicants' amendment to the claims and/or the base claim(s).
- 18) The rejection of claims 8, 18, 22, 25 and 26 made in paragraph 11 of the Office Action mailed 07/12/02 (paper no. 18) under 35 U.S.C § 112, first paragraph, as being non-enabled, is withdrawn.
- 19) The rejection of claim 4 made in paragraph 13(a) of the Office Action mailed 07/12/02 (paper no. 18) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 20) The rejection of claims 4, 7, 18 and 21 made in paragraph 13(b) of the Office Action mailed 07/12/02 (paper no. 18) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims and/or the base claim.
- 21) The rejection of claims 8, 19, 22, 25 and 26 made in paragraph 13(c) of the Office Action mailed 07/12/02 (paper no. 18) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim(s).
- 22) The rejection of claims 1, 7, 21 and 24 made in paragraph 15 of the Office Action mailed 07/12/02 (paper no. 18) under 35 U.S.C § 102(b) as being anticipated by Yamano *et al.* (*J. Antimicrob. Chemother.* 26: 175-184, 1990), or Yoshinori *et al.* (*Appl. Microbiol. Biotechnol.* 40: 892-897, 1994), or Brown *et al.* (*J. Bacteriol.* 177: 6536-6544, 1995), or Yamaguchi *et al.* (*Jpn. J. Bacteriol.* 41: 701-708, 1986), or Sompolinsky *et al.* (*Acta Pathol. Microbiol. Scand. Sect. B* 88: 143-149, 1980), or Barbhaiya *et al.* (*FEMS Microbiol. Lett.* 51: 169-172, 1988), or Meyer *et al.* (*Mol. Microbiol.* 4: 1401-1405, 1990), or Fernandes *et al.* (*Infect. Immun.* 33: 527-32, 1981), is withdrawn in light of Applicants' amendment to the claims and/or the base claim(s).
- 23) The rejection of claims 1, 7 and 9 made in paragraph 16 of the Office Action mailed 07/12/02 (paper no. 18) under 35 U.S.C § 102(b) as being anticipated by Yamano *et al.* (*J. Antimicrob. Chemother.* 26: 175-184, 1990), or Yoshinori *et al.* (*Appl. Microbiol. Biotechnol.* 40: 892-897, 1994), or Yamaguchi *et al.* (*Jpn. J. Bacteriol.* 41: 701-708, 1986), or Barbhaiya *et al.* (*FEMS Microbiol. Lett.* 51: 169-172, 1988), or Meyer *et al.* (*Mol. Microbiol.* 4: 1401-1405, 1990), is

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withdrawn in light of Applicants' amendment to the claims and/or the base claim(s).

24) The rejection of claims 1 and 4 made in paragraph 17 of the Office Action mailed 07/12/02 (paper no. 18) under 35 U.S.C § 102(b) as being anticipated by Sipos *et al.* (*Infect. Immun.* 59: 3219-3226, 1991), is withdrawn in light of Applicants' amendment to the claims and/or the base claim(s).

25) The rejection of claims 1, 4, 21 and 24 made in paragraph 18 of the Office Action mailed 07/12/02 (paper no. 18) under 35 U.S.C § 102(b) as being anticipated by Hancock *et al.* (WO 93/24636), is withdrawn in light of Applicants' amendment to the claims and/or the base claim(s).

26) The rejection of claims 1, 7, 19-21, 24 and 27 made in paragraph 20 of the Office Action mailed 07/12/02 (paper no. 18) under 35 U.S.C § 103(a) as being unpatentable over Yamano *et al.* (*J. Antimicrob. Chemother.* 26: 175-184, 1990), or Yoshinori *et al.* (*Appl. Microbiol. Biotechnol.* 40: 892-897, 1994), or Brown *et al.* (*J. Bacteriol.* 177: 6536-6544, 1995), or Yamaguchi *et al.* (*Jpn. J. Bacteriol.* 41: 701-708, 1986), or Sompolinsky *et al.* (*Acta Pathol. Microbiol. Scand. Sect. B* 88: 143-149, 1980), or Barbhaiya *et al.* (*FEMS Microbiol. Lett.* 51: 169-172, 1988), or Meyer *et al.* (*Mol. Microbiol.* 4: 1401-1405, 1990), or Fernandes *et al.* (*Infect. Immun.* 33: 527-32, 1981), or Hancock *et al.* (WO 93/24636), or Sipos *et al.* (*Infect. Immun.* 59: 3219-3226, 1991), is withdrawn in light of Applicants' amendment to the claims and/or the base claim(s).

New Rejection(s)

Applicants are asked to note the following new rejection(s) made in this Office. The new rejections are necessitated by Applicants' amendments and/or the submission of a new claim.

Rejection(s) under 35 U.S.C. 101

27) 35 U.S.C. § 101 states:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this cycle.

28) Claim 4 is rejected under 35 U.S.C. § 101 as being directed to a non-statutory subject matter.

Claim 4, as written, does not sufficiently distinguish over amino acids as they exist naturally, for example, on a microbe, because the claim does not particularly point out any non-naturally occurring differences between the claimed product and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject

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matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claim(s) should be amended to indicate the hand of the inventor, e.g., by insertion of 'An isolated fragment ... ---' as described in the instant application. See MPEP 2105.

Rejection(s) under 35 U.S.C. 112, First Paragraph

29) Claims 1, 4, 7-9, 18-22 and 24-27 are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1, as amended, includes the following new limitation:

"Glu Glu Lys Xaa Xaa Leu (SEQ ID NO: 3);
Xaa Glu Glu Lys Thr Pro Leu (SEQ ID NO: 4); and
Val Val Xaa Asn Ala (SEQ ID NO: 5)."

Applicants state the peptide fragments of SEQ ID NOS: 3-5 are supported by the specification at page 2, lines 11-16. However, this part of the specification neither identified these specific peptide fragments nor provides descriptive support for the same. Therefore, the above-identified limitations in the claim are considered to be new matter. An amendment to a claim must have antecedent basis in the original disclosure. See 37 C.F.R 1.121. MPEP 2163.06 states that Applicants should specifically point out the support for any amendments made to the disclosure. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P. 608.04 to 608.04(c).

Applicants are invited to point to the descriptive support in specific part(s) of the disclosure, as originally filed, for the limitations identified above, or to remove the new matter from the claims and/or the base claim(s).

Rejection(s) under 35 U.S.C. 112, Second Paragraph

30) Claims 1, 4, 8, 9, 21, 22 and 24-27 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 1 is vague and indefinite in the recitation "Xaa" without particularly pointing

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out what exactly does "Xaa" stand for. If Xaa represents an unknown amino acid as indicated in that the specification, for clarity, Applicants should include the limitation --wherein Xaa is an unknown amino acid-- after (SEQ ID NO: 2) in claim 1.

(b) Claim 9 is confusing in the recitation "*P. aeruginosa* protein or protein fragment", because it is unclear whether the 'protein fragment' is a fragment of the earlier recited "*P. aeruginosa* protein", or whether it is a fragment of an unrelated protein. If Applicants meant the former, then Applicants should consider replacing the recitation with --*P. aeruginosa* protein or a fragment of said protein--.

(c) Claims 4, 8, 21, 22 and 24-27, which depend directly or indirectly from claim 1 or 9, are also rejected under 35 U.S.C § 112, second paragraph, as being indefinite, because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. 102

31) The following is a quotation of the appropriate paragraph(s) of 35 U.S.C. § 102 that form the basis for the rejection(s) under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) The invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

32) Claims 1, 4, 8, 9, 21, 22 and 24-27 are rejected under 35 U.S.C § 102(e) as being anticipated by Green *et al.* (US 6,100,380, filed 06/07/1995) as evidenced by Foster *et al.* (US 6,436,391, filed 01/31/1997).

Claim 1 has been included in this rejection only to the extent that claim 4 includes the limitation 'claim 1'.

The transitional limitation "comprises" similar to the limitations, such as, "has", "includes," "contains," or "characterized by," represents open-ended claim language and therefore does not exclude additional, unrecited elements. See M.P.E.P 2111.03 [R-1]. See *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). On the

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other hand, the limitation "consisting of" represents closed claim language and excludes any element, step, or ingredient not specified in the claim. *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948).

Green *et al.* disclosed a therapeutic or prophylactic immunomodulating Gly-Lys dipeptide preparation in saline (see abstract and Example 7). The prior art Gly-Lys dipeptide serves as a fragment of the instantly recited SEQ ID NO: 2. The peptide is present as a pharmaceutical composition in a pharmaceutically acceptable carrier, such as, saline, water, lipoprotein, glycine (i.e., protein fragment), or interferon. The peptide is also formulated as a tablet, capsule or suppository (see column 5). Green *et al.* also disclosed a vaccine composition comprising the peptide, Thr-Ala-Glu-Glu-Lys, which elicited an immune response in fish (see Example 9). That Green's interferon intrinsically serves as an adjuvant is inherent from the disclosure of Green *et al.* in light of what was well known in the art at the time of the invention. For instance, Foster *et al.* taught that interferon serves as an adjuvant when administered with an antigen (see abstract; and columns 1 and 2).

Claims 1, 4, 8, 9, 21, 22 and 24-27 are anticipated by Green *et al.*

Rejection(s) under 35 U.S.C. 103

33) Claims 1, 4, 8, 9, 19, 20 and 36 are rejected under 35 U.S.C § 103(a) as being unpatentable over Green *et al.* (US 6,100,380, filed 06/07/1995).

Claim 1 has been included in this rejection only to the extent that claim 4 includes the limitation 'claim 1'.

The disclosure of Green *et al.* is explained above, which teaches the peptide in the form of tablets and capsules, but does not expressly mention the term 'kit'.

However, assembling a tablet package or kit using an art-known peptide is conventional and routinely practiced in the art. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to produce a package kit for sale of Green's tablets containing the peptide, with a reasonable expectation of success. A skilled artisan would have been motivated to produce the instant invention for the expected benefit of making readily available Green's peptide tablets, or for commercializing Green's peptide tablets.

Claims 4, 8, 9, 19, 20 and 36 are *prima facie* obvious over the prior art of record.

Objection(s)

34) Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is noted that claim 4 depends from claim 1 which does not recite any 'fragment'.

Remarks

35) Claims 1, 4, 7-9, 18-22 and 24-27 stand rejected. Claim 1, to the extent it encompasses SEQ ID NO: 2, and claims 7 and 18 are free of prior art currently of record.

36) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

37) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

38) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to

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Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

March, 2003


S. DEVI, PH.D.
PRIMARY EXAMINER